DEPARTMENT OF COMMERCE

Bureau of Industry and Security

15 CFR Parts 740, 742 and 774

[Docket No. 220909-0188]

RIN 0694-AI21

Implementation of Australia Group Decisions from 2021 and 2022 Virtual Meetings: Controls on Marine Toxins, Plant Pathogens and Biological Equipment

AGENCY: Bureau of Industry and Security, Commerce.

ACTION: Final rule.

SUMMARY: The Bureau of Industry and Security (BIS) publishes this final rule to amend the Export Administration Regulations (EAR) to reflect decisions made at the November 2021 and March 2022 Australia Group (AG) Virtual Implementation Meetings and the AG Plenary Meeting held in July 2022. The amendments include revisions to certain Export Control Classification Numbers to clarify the controls on genetic elements and genetically modified organisms and the scope of the exclusion that applies to medical isolators "specially designed" for barrier nursing or transportation of infected patients; and makes clarifications by adding four naturally occurring, dual-use marine toxins (specifically, brevetoxins, gonyautoxins, nodularins

and palytoxin) and removing cholera toxin. The addition of these four toxins is consistent with Section 1758 of the Export Control Reform Act of 2018 (ECRA) regarding emerging and foundational technologies. Finally, this rule also includes amendments to reflect the AG Plenary updates to the nomenclature of certain bacteria and fungi, and the clarification of the definition of "disinfected" as it applies to certain biological equipment.

DATES: This rule is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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SUPPLEMENTARY INFORMATION:

Background

The Bureau of Industry and Security (BIS) is amending the Export Administration Regulations (EAR) (15 CFR parts 730-774) to reflect the decisions made at the November 2021 and March 2022 Australia Group (AG) Virtual Implementation Meetings and the AG Plenary Meeting held in Paris, France, from July 4 through July 8, 2022. The AG is a multilateral forum consisting of 42 participating countries and the European Union. These participants maintain export controls on a list of chemicals, biological agents, and related equipment and technology that could be used in a chemical or biological weapons program. The AG periodically reviews items on its control list to enhance the effectiveness of participating governments' national controls and to achieve greater harmonization among these controls.

At the November 2021 AG Virtual Implementation Meeting, the AG revised its "Control List of Dual-Use Biological Equipment and Related Technology and Software" to clarify the scope of the exclusion that applies to medical isolators "specially designed" for barrier nursing or transportation of infected patients.

Consistent with decisions made at the AG's March 2022 Virtual Implementation Meeting, two AG common control lists (i.e., the list of "Human and Animal Pathogens and Toxins" and the "List of Plant Pathogens for Export Control") were updated to clarify that the controls on genetic elements and genetically modified organisms include*, inter alia*, any gene(s) or translated product(s) specific to any controlled virus. Previously, the control text for viral genetic elements referred only to the risk posed by the nucleic acid sequence itself, and not to transcribed or translated products.

The AG also made changes to three of its common control lists to reflect the decisions made at its July 2022 Plenary Meeting. The AG revised its list of "Human and Animal Pathogens and Toxins" to add four naturally occurring, dual-use marine toxins (specifically, brevetoxins, gonyautoxins, nodularins and palytoxin) and remove cholera toxin. The AG also revised its "Control List of Dual-Use Biological Equipment and Related Technology and Software" by clarifying the definition of "disinfected" to more closely reflect the use of this term by the scientific and industrial communities. In addition, the AG revised its "List of Plant Pathogens for Export Control" to update the nomenclature for certain bacteria and fungi.

I. EAR changes reflecting the November 2021 AG Virtual Implementation Meeting decision

Amendments to ECCN 2B352

Consistent with the decision made at the November 2021 AG Virtual Implementation Meeting, this rule amends ECCN 2B352 to reflect changes in the Notes to the AG controls on biocontainment chamber, isolators and biological safety cabinets described in the "Control List

of Dual-Use Biological Equipment and Related Technology and Software." Specifically, *Note 2 to 2B352.g.2* is revised to clarify that this ECCN controls any isolator having all of the characteristics described in 2B352.g.2.a through g.2.d, regardless of its intended use and its designation, except for medical isolators "specially designed" for barrier nursing or transportation of infected patients. Additional amendments to this ECCN, which reflect decisions made at the July 2022 AG Plenary Meeting, are described later in the preamble of this rule.

II. EAR changes reflecting the March 2022 AG Virtual Implementation Meeting decision

Amendments to Export Control Classification Number (ECCN) 1C353

Consistent with the decision made at the March 2022 AG Virtual Implementation Meeting, this rule amends paragraph a.1 of ECCN 1C353 on the Commerce Control List (CCL), in Supplement No. 1 to part 774 of the EAR, to clarify that the controls on genetic elements and genetically modified organisms include, *inter alia*, any gene(s) or translated product(s) specific to any controlled virus. Prior to the publication of this final rule, this ECCN did not explicitly state that its controls on viral genetic elements also included translated product(s) specific to any controlled virus. The control text in ECCN 1C353.a previously referred to transcribed or translated product(s) only with respect to bacterial and fungal genetic elements described in paragraph a.2.a.

III. EAR changes reflecting the July 2022 AG Plenary Meeting decisions

Amendments to ECCN 1C350

This final rule amends ECCN 1C350, consistent with the July 2022 AG Plenary Meeting update to the "Export Control List: Chemical Weapons Precursors," by adding a clarification to *Technical Note 3* in this ECCN. This change is also consistent with a recommendation by the Organization for the Prohibition of Chemical Weapons (OPCW) to control all stereoisomers and isotopically-labeled forms of scheduled chemicals, even if they have different CAS numbers. Specifically, this rule revises the parenthetical "(e.g., hydrates)," in the second sentence of *Technical Note 3*, to read "(e.g., hydrates, isotopically-labeled forms or all possible stereoisomers)."

Amendments to ECCN 1C351

This final rule reflects the recent updates to the AG "Human and Animal Pathogens and Toxins" common control list, as described above, by amending ECCN 1C351 to add four marine toxins (brevetoxins, gonyautoxins, nodularins and palytoxin) and remove cholera toxin. Specifically, the four marine toxins are added in alphabetical order to ECCN 1C351.d, where they are controlled for chemical/biological (CB) and anti-terrorism (AT) reasons. Certain other toxins in this ECCN are renumbered, accordingly, to reflect the addition of the marine toxins and the removal of cholera toxin.

This rule also makes conforming changes elsewhere in ECCN 1C351 to update references to certain toxins (i.e., in the CW Reason for Control paragraph, License Requirements Notes 1 and 2, the License Exception STA eligibility paragraph and the Related Controls paragraph). Similar conforming amendments to the Chemical Weapons Convention (CWC) and License Exception Strategic Trade Authorization (STA) provisions in the EAR are described below.

As described in more detail below, BIS identified the synthesis and collection of the four marine toxins for evaluation according to the criteria in Section 1758 of the Export Control Reform Act of 2018 (ECRA), 50 U.S.C. 4801-4852, pertaining to emerging and foundational technologies. Other considerations prompted the decision to remove cholera toxin from the list of "Human and Animal Pathogens and Toxins." At the time of its inclusion on this AG common control list, cholera toxin did not have any significant commercial or medical uses. However, in recent years, there has been a significant increase in biomedical research involving cholera toxins and in the use of cholera toxin in biomedical applications. Furthermore, cholera toxin, by itself (i.e., in the absence of live bacteria), is known to have limited cytotoxicity (e.g., compared to other toxins such as botulinum, saxitoxin, or ricin), and cannot be transmitted from person to person. Cholera toxin has not been the major focus of a biological weapons research program, although it may have been evaluated for such purposes. Consequently, the removal of chemical/biological (CB) controls on cholera toxins is not expected to have a significant impact on the proliferation, development, production or use of biological weapons, nor would the relative costs of such controls (e.g., in terms of their impact on public health and on biomedical and related research) be justified going forward.

Expansion of ECCN 1E001 controls.

Although this rule does not amend ECCN 1E001 (which controls, *inter alia*, "technology" for the "development" or "production" of the human and animal pathogens and "toxins" described in ECCN 1C351), the heading of ECCN 1E001 indicates that, with limited exceptions, ECCN 1E001 controls "technology for the "development" or "production" of items listed under Category 1C of the CCL. Consequently, ECCN 1E001 now controls "technology" for the "development" or "production" of the four marine toxins that are being added to ECCN 1C351 by this rule.

Other conforming amendments to reflect the reordering of toxins in ECCN 1C351.d.

This rule amends § 740.20—License Exception Strategic Trade Authorization (STA) to make conforming changes to the ECCN 1C351.d references in paragraph (b)(2)(v) and paragraph (b)(2)(vi). Specifically, § 740.20(b)(2)(v) is amended to reference the exclusion of ECCN 1C351.d.14 and d.15 items from License Exception STA eligibility, consistent with the proposed renumbering of ricin and saxitoxin (which were previously controlled under ECCN 1C351.d.11 and d.12, respectively). Similarly, § 740.20(b)(2)(vi) is amended, consistent with the renumbering of the toxins in ECCN 1C351.d, by revising the references to the ECCN 1C351.d toxins that are authorized (with certain limitations) under License Exception STA to destinations indicated in Country Group A:5 (see Supplement No. 1 to part 740 of the EAR).

This rule also makes conforming changes to § 742.18—Chemical Weapons Convention (CWC) and ECCN 1C991 (Vaccines, immunotoxins, medical products, diagnostic and food testing kits) to reflect the renumbering of the toxins in ECCN 1C351.d. Specifically, § 742.18(a)(1), (b)(1)(i), and (b)(1)(ii) and (iii) are amended to reference ECCN 1C351.d.14 and d.15, consistent with the renumbering of ricin and saxitoxin described above. In ECCN 1C991, 1C991.c.1 and .e are amended to make conforming changes to the references therein to ECCN 1C351 that are affected by the renumbering of the toxins in ECCN 1C351.d.

None of the conforming amendments described above changes the scope of the controls in the affected EAR provisions.

Amendments to ECCN 1C354

This final rule reflects the AG Plenary changes to the "List of Plant Pathogens for Export Control," which updated the nomenclature for certain bacteria and fungi. Specifically, this rule amends ECCN 1C354.a by updating the nomenclature of the bacteria "*Xanthomonas axonopodis* pv. *citri* (*Xanthomonas campestris* pv. *citri* A) (*Xanthomonas campestris* pv. *citri*)" and "*Clavibacter michiganensis* subspecies *sepedonicus* (syn. *Corynebacterium michiganensis* subspecies *sepedonicum or Corynebacterium sepedonicum*)" to read "*Xanthomonas citri* pv. *citri (Xanthomonas axonopodis* pv. *citri, Xanthomonas campestris* pv. *citri)*" and "*Clavibacter michiganensis* subsp. *sepedonicus*, (*Clavibacter sepedonicus*, *Clavibacter michiganense* subsp. *sepedonicus*, *Corynebacterium michiganensis* subsp. *sepedonicum*, *Corynebacterium sepedonicum*)," respectively. In addition, ECCN 1C354.b is amended to update the nomenclature of the fungi "*Cochliobolus miyabeanus* (*Helminthosporium oryzae*)" and "*Microcyclus ulei* (syn. *Dothidella ulei*)" to read "*Bipolaris oryzae* (*Cochliobolus miyabeanus*, *Helminthosporium oryzae*)" and "*Pseudocercospora ulei* (*Microcyclus ulei, Dothidella ulei*)," respectively. To maintain the listing of these fungi in alphabetical order, "*Bipolaris oryzae* (*Cochliobolus miyabeanus*, *Helminthosporium oryzae*)," which was previously controlled under ECCN 1C354.b.2, is now controlled under ECCN 1C354.b.1 and "*Colletotrichum kahawae* (*Colletotrichum coffeanum* var. *virulans*)," which was previously controlled under ECCN 1C354.b.1, is now controlled under ECCN 1C354.b.2.

Amendments to ECCN 2B352

In addition to the ECCN 2B352 amendments described above (see discussion of amendments per the November 2021 AG Virtual Implementation Meeting decision), this final rule amends ECCN 2B352 to reflect the recent updates to the AG "Control List of Dual-Use Biological Equipment and Related Technology and Software," by revising the definition of "disinfected" to more closely reflect the use of this term by the scientific and industrial

communities. Specifically, this rule amends the *Technical Note* following ECCN 2B352.d.2 by revising the definition of "disinfected" to indicate that this term "denotes a process to reduce the number of microorganisms, but not usually of bacterial spores, through the use of chemical agents, without necessarily killing or removing all organisms." This change eliminates what appeared to be a disparity between the commonly accepted use of this term in scientific and industrial circles and the previous AG definition, wherein the latter described both "disinfection" and "sterilization" as being distinct from "sanitization" (with "sanitization" referring to cleaning procedures designed to lower the microbial content of equipment without necessarily achieving elimination of all microbial infectivity or viability).

Marine toxins identified for evaluation under Section 1758 of ECRA

In advance of the 2022 AG Plenary meeting, BIS identified the synthesis and collection of the four marine toxins addressed in this final rule for evaluation according to the criteria in Section 1758 of ECRA, pertaining to emerging and foundational technologies. These marine toxins have the potential (through either accidental or deliberate release) to cause casualties in humans or animals, degrade equipment, or damage crops or the environment. Because these toxins are now capable of being more easily isolated and purified due to novel synthesis methods and equipment, BIS determined that the absence of export controls on the toxins could be exploited for biological weapons purposes.

Consistent with the emerging and foundational technologies notice and comment requirements in Section 1758(a)(2)(C) of ECRA (50 U.S.C. 4817(a)(2)(C)), BIS published a proposed rule on May 23, 2022 (87 FR 31195), to provide the public with notice and the opportunity to comment on its proposal to amend ECCN 1C351 on the CCL to add these marine toxins to ECCN 1C351.

Comments submitted in response to BIS's May 23 proposed rule

BIS received comments from two respondents in response to the publication of its May 23 proposed rule. The comments from these respondents, together with BIS's responses, are described below.

Comment: One respondent indicated that clarification was needed concerning whether any of the four marine toxins proposed for control have an identified and specific biological synthesis pathway. In the respondent's opinion, if this were the case, then certain genes or gene clusters may become subject to control as a result of imposing controls on the toxin. If not, then the respondent thought it unlikely that any genes or gene clusters would become subject to control as a consequence of controlling the toxin.

BIS response: ECCN 1C353.a.3 controls any genetically modified organism that contains, or any genetic element that codes for, any toxins (or their subunits) controlled by 1C351.d. Genetically modified organisms and genetic elements are defined in *Technical Notes 1 and 2*, respectively, in ECCN 1C353. To the extent that any genes and gene clusters became subject to control under ECCN 1C353, as a result of the imposition of controls on the four marine toxins and their subunits under ECCN 1C351.d, they would be among the genetically modified organisms and genetic elements described in ECCN 1C353.a.3. BIS believes that the controls described in ECCN 1C353.a.3 are sufficiently clear in this respect and, consequently, that no further clarification is necessary.

Comment: Another respondent submitted comments that addressed COVID vaccines and treatments within the context of the World Trade Organization's Trade-Related Aspects of Intellectual Property Rights (TRIPS).

BIS response: These TRIPS-based comments were not responsive to the request for comments in BIS's May 23 proposed rule, as they were focused almost exclusively on the potential relationship between intellectual property rights and the availability of COVID vaccines within various countries. Furthermore, the comments did not specifically address whether and, if so, how export controls would impact the availability of such vaccines in those countries. Consequently, these comments are not addressed in this final rule.

Saving Clause

Shipments of items removed from eligibility for export, reexport or transfer (in-country) under a license exception or without a license (i.e., under the designator "NLR") as a result of this regulatory action that were on dock for loading, on lighter, laden aboard an exporting carrier, or en route aboard a carrier to a port of export, on [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER], pursuant to actual orders for export, reexport or transfer (in-country) to a foreign destination, may proceed to that destination under the previously applicable license exception or without a license (NLR) so long as they are exported, reexported or transferred (in-country) before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Any such items not actually exported, reexported or transferred (in-country) before midnight, on [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER], require a license in accordance with this regulation.

"Deemed" exports of "technology" and "source code" removed from eligibility for export

under a license exception or without a license (under the designator "NLR") as a result of this regulatory action may continue to be made under the previously available license exception or without a license (NLR) before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Beginning at midnight on [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER], such "technology" and "source code" may no longer be released, without a license, to a foreign national subject to the "deemed" export controls in the EAR when a license would be required to the home country of the foreign national in accordance with this regulation.

Export Control Reform Act of 2018

The Export Control Reform Act of 2018 (ECRA), as amended, codified at 50 U.S.C. 4801–4852, serves as the authority under which BIS issues this final rule.

Rulemaking Requirements

1. Executive Orders 13563 and 12866 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including: potential economic, environmental, public health and safety effects; distributive impacts; and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits and of reducing costs, harmonizing rules, and promoting flexibility. This final rule has been designated a "significant regulatory action," although not economically significant, under section 3(f) of Executive Order 12866. Accordingly, this final rule has been reviewed by the Office of Management and Budget (OMB).

2. Notwithstanding any other provision of law, no person is required to respond to,

nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq*.) (PRA), unless that collection of information displays a currently valid Office of Management and Budget (OMB) Control Number. Although this rule makes important changes to the EAR for items controlled for chemical/biological reasons, BIS believes that the overall increases in burdens and costs associated with the following information collections due to this rule will be minimal:

- OMB control number 0694–0088 (Simplified Network Application Processing System) – this collection includes license applications and carries a burden estimate of 29.4 minutes per manual or electronic submission;
- OMB Control Number 0694-0096 (Five Year Records Retention Period) – this collection includes recordkeeping requirements and carries a burden estimate of less than 1 minute per response;
- OMB Control Number 0607-0152 (Automated Export System (AES) Program) – this collection carries a burden hour estimate of 3 minutes per electronic submission and contains the Electronic Export Information (EEI) filing requirements under the Automated Export System (AES).

Additional information regarding these collections of information, including all background materials, can be found at https:/www.reginfo.gov/public/do/PRAMain and using the search function to enter either the title of the collection or the OMB Control Number.

3. This final rule does not contain policies with federalism implications as that term is defined in Executive Order 13132.

4. As stated in the preamble of this final rule, the amendments contained in this rule

reflect decisions made at the Australia Group (AG) Plenary Meeting held in Paris, France, from July 4 through July 8, 2022. Therefore, pursuant to Section 1762 of the Export Control Reform Act of 2018 (ECRA) (50 U.S.C. Sec. 4821), this action is exempt from the Administrative Procedure Act (APA) (5 U.S.C. 553) requirements for notice of proposed rulemaking, opportunity for public participation and delay in effective date.

Because a notice of proposed rulemaking and an opportunity for public comment are not required to be given for this final rule by the APA or any other law, the analytical requirements of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq*.), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA) (5 U.S.C. 601 *et seq*.), are not applicable.

Consistent with the emerging and foundational technologies notice and comment requirements in Section 1758(a)(2)(C) of ECRA (50 U.S.C. 4817(a)(2)(C)), BIS published a proposed rule on May 23, 2022 (87 FR 31195), to provide the public with notice and the opportunity to comment on its proposal to amend ECCN 1C351 on the Commerce Control List (CCL) to add four marine toxins (i.e., brevetoxins, gonyautoxins, nodularins and palytoxin) to ECCN 1C351, the synthesis and collection of which BIS had identified for evaluation according to the criteria in Section 1758 of the Export Control Reform Act of 2018 (ECRA) pertaining to emerging and foundational technologies. In addition, consistent with the Regulatory Flexibility Act, BIS prepared an initial regulatory flexibility analysis (IRFA) of the impact that the proposed rule, if adopted, would have on small businesses. The IRFA prepared by BIS requested comments on the analyses and conclusions contained therein, including the overall conclusion that the amendments in BIS's May 23 proposed rule would not have a significant economic impact on a substantial number of small entities.

BIS received comments from two respondents on its May 23 proposed rule – these comments and BIS's responses are summarized in the preamble of this final rule. BIS did not receive any comments in response to the analyses and conclusions contained in the IRFA for its May 23 proposed rule. Accordingly, no regulatory flexibility analysis is required for this final rule, and none has been prepared.

List of Subjects

15 CFR Part 740

Administrative practice and procedure, Exports Reporting and recordkeeping requirements, Terrorism.

15 CFR Part 742

Exports, Terrorism.

15 CFR Part 774

Exports, Reporting and recordkeeping requirements, Terrorism.

For the reasons stated in the preamble, parts 740, 742, and 774 of the Export Administration Regulations (15 CFR parts 730-774) are amended as follows:

PART 740—LICENSE EXCEPTIONS

1. The authority citation for part 740 continues to read as follows:

Authority: 50 U.S.C. 4801–4852; 50 U.S.C. 4601 *et seq*.; 50 U.S.C. 1701 *et seq*.; 22

U.S.C. 7201 *et seq*.; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783.

2. Section 740.20 is amended by revising paragraph (b)(2)(v) and paragraph (b)(2)(vi) introductory text to read as follows:

§ 740.20 License Exception Strategic Trade Authorization (STA).

* * * * *

(b) * * *

(2) * * *

(v) License Exception STA may not be used for any item controlled by ECCN 1C351.a, .b, .c, .d.14, .d.15 or .e, ECCNs 1C353, 1C354, 1E001 (i.e., for technology, as specified in ECCN 1E001, for items controlled by ECCN 1C351.a, .b, .c, .d.14, .d.15 or .e or ECCNs 1C353 or 1C354) or ECCN 1E351.

(vi) Toxins controlled by ECCN 1C351.d.1 through 1C351.d.13 and 1C351.d.16 through 1C351.d.21 are authorized under License Exception STA to destinations indicated in Country Group A:5 (See supplement no. 1 to this part 740), subject to the following limits. For purposes of this paragraph (b)(2)(vi), all such toxins that are sent from one exporter, reexporter or transferor to a single end-user, on the same day, constitute one shipment.

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PART 742—CONTROL POLICY—CCL BASED CONTROLS

3. The authority citation for part 742 continues to read as follows:

Authority: 50 U.S.C. 4801–4852; 50 U.S.C. 4601 *et seq*.; 50 U.S.C. 1701 *et seq*.; 22 U.S.C. 3201 *et seq*.; 42 U.S.C. 2139a; 22 U.S.C. 7201 *et seq*.; 22 U.S.C. 7210; Sec. 1503, Pub. L. 108–11, 117 Stat. 559; E.O. 12058, 43 FR 20947, 3 CFR, 1978 Comp., p. 179; E.O. 12851, 58 FR 33181, 3 CFR, 1993 Comp., p. 608; E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Presidential Determination 2003–23, 68 FR 26459, 3 CFR, 2004 Comp., p. 320;

Notice of November 10, 2021, 86 FR 62891 (November 12, 2021).

4. Section 742.18 is amended by revising paragraph (a)(1), paragraph (b)(1)(i) introductory text, and paragraphs (b)(1)(ii) and (iii) to read as follows:

§ 742.18 Chemical Weapons Convention (CWC or Convention).

* * * * *

(a) * * *

(1) Schedule 1 chemicals and mixtures controlled under ECCN 1C351. A license is required for CW reasons to export or reexport Schedule 1 chemicals controlled under ECCN 1C351.d.14 or .d.15 to all destinations including Canada. CW applies to 1C351.d.14 for ricin in the form of Ricinus Communis AgglutininII (RCA_{II}), which is also known as ricin D or Ricinus Communis LectinIII (RCL_{III}), and Ricinus Communis LectinIV (RCL_{IV}), which is also known as ricin E. CW applies to 1C351.d.15 for saxitoxin identified by C.A.S. #35523-89-8. (Note that the advance notification procedures and annual reporting requirements described in § 745.1 of the EAR also apply to exports of Schedule 1 chemicals.)

* * * * *

(b) * * *

(1) * * *

(i) *Exports to States Parties to the CWC*. Applications to export Schedule 1 Chemicals controlled under ECCN 1C351.d.14 or .d.15 to States Parties to the CWC (destinations listed in supplement no. 2 to part 745 of the EAR) generally will be denied, unless all of the following conditions are met:

* * * * *

(ii) *Exports to States not party to the CWC*. Applications to export Schedule 1 chemicals controlled under ECCN 1C351.d.14 or .d.15 to States not Party to the CWC (destinations not listed in supplement no. 2 to part 745 of the EAR) generally will be denied, consistent with U.S. obligations under the CWC to prohibit exports of these chemicals to States not Party to the

CWC.

(iii) *Reexports*. Applications to reexport Schedule 1 chemicals controlled under ECCN 1C351.d.14 or .d.15 generally will be denied to all destinations (including both States Parties to the CWC and States not Party to the CWC).

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PART 774—THE COMMERCE CONTROL LIST

5. The authority citation for part 774 continues to read as follows:

Authority: 50 U.S.C. 4801-4852; 50 U.S.C. 4601 *et seq*.; 50 U.S.C. 1701 *et seq*.; 10 U.S.C. 8720; 10 U.S.C. 8730(e); 22 U.S.C. 287c, 22 U.S.C. 3201 *et seq*.; 22 U.S.C. 6004; 42 U.S.C. 2139a; 15 U.S.C. 1824; 50 U.S.C. 4305; 22 U.S.C. 7201 *et seq*.; 22 U.S.C. 7210; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783.

6. In Supplement No. 1 to Part 774 (the Commerce Control List), Category 1, revise ECCNs 1C350, 1C351, 1C353, 1C354, 1C991, and 2B352 to read as follows:

Supplement No. 1 to Part 774—The Commerce Control List

* * * * *

1C350 Chemicals that may be used as precursors for toxic chemical agents (see List of Items Controlled).

License Requirements

Reason for Control: CB, CW, AT

Control(s)	Country chart (See Supp. No. 1 to part 738)
CB applies to entire entry	CB Column 2

CW applies to 1C350.b and .c. The Commerce Country Chart is not designed to determine licensing requirements for items controlled for CW reasons. A license is required, for CW reasons, to export or reexport Schedule 2 chemicals and mixtures identified in 1C350.b to States not Party to the CWC (destinations not listed in Supplement No. 2 to part 745 of the EAR). A license is required, for CW reasons, to export Schedule 3 chemicals and mixtures identified in 1C350.c to States not Party to the CWC, unless an End-Use Certificate issued by the government of the importing country has been obtained by the exporter prior to export. A license is required, for CW reasons, to reexport Schedule 3 chemicals and mixtures identified in 1C350.c from a State not Party to the CWC to any other State not Party to the CWC. (See § 742.18 of the EAR for license requirements and policies for toxic and precursor chemicals controlled for CW reasons. See § 745.2 of the EAR for End-Use Certificate requirements that apply to exports of Schedule 3 chemicals to countries not listed in Supplement No. 2 to part 745 of the EAR.)

AT applies to entire entry. The Commerce Country Chart is not designed to determine licensing requirements for items controlled for AT reasons in 1C350. A license is required, for AT reasons, to export or reexport items controlled by 1C350 to a country in Country Group E:1 of Supplement No. 1 to part 740 of the EAR. (See part 742 of the EAR for additional information on the AT controls that apply to Iran, North Korea, and Syria. See part 746 of the EAR for additional information on sanctions that apply to Iran, North Korea, and Syria.)

License Requirement Notes

1. SAMPLE SHIPMENTS: Subject to the following requirements and restrictions, a license is not required for sample shipments when the cumulative total of these shipments does not exceed a 55-gallon container or 200 kg of a single chemical to any one consignee during a calendar year. A consignee that receives a sample shipment under this exclusion may not resell, transfer,

or reexport the sample shipment, but may use the sample shipment for any other legal purpose unrelated to chemical weapons.

a. Chemicals Not Eligible:

A. [Reserved]

B. CWC Schedule 2 chemicals (States not Party to the CWC). No CWC Schedule 2 chemical or mixture identified in 1C350.b is eligible for sample shipment to States not Party to the CWC (destinations not listed in Supplement No. 2 to part 745 of the EAR) without a license.

b. Countries Not Eligible: Countries in Country Group E:1 of Supplement No. 1 to part 740 of the EAR are not eligible to receive sample shipments of any chemicals controlled by this ECCN without a license.

c. Sample shipments that require an End-Use Certificate for CW reasons: No CWC Schedule 3 chemical or mixture identified in 1C350.c is eligible for sample shipment to States not Party to the CWC (destinations not listed in Supplement No. 2 to part 745 of the EAR) without a license, unless an End-Use Certificate issued by the government of the importing country is obtained by the exporter prior to export (see § 745.2 of the EAR for End-Use Certificate requirements).

d. Sample shipments that require a license for reasons set forth elsewhere in the EAR: Sample shipments, as described in this Note 1, may require a license for reasons set forth elsewhere in the EAR. See, in particular, the end-use/end-user restrictions in part 744 of the EAR, and the restrictions that apply to embargoed countries in part 746 of the EAR.

e. Annual report requirement. The exporter is required to submit an annual written report for shipments of samples made under this Note 1. The report must be on company

letterhead stationery (titled "Report of Sample Shipments of Chemical Precursors" at the top of the first page) and identify the chemical(s), Chemical Abstract Service Registry (C.A.S.) number(s), quantity(ies), the ultimate consignee's name and address, and the date of export for all sample shipments that were made during the previous calendar year. The report must be submitted no later than February 28 of the year following the calendar year in which the sample shipments were made, to: U.S. Department of Commerce, Bureau of Industry and Security, 14th Street and Pennsylvania Ave., NW, Room 2099B, Washington, DC 20230, Attn: "Report of Sample Shipments of Chemical Precursors."

2. MIXTURES:

a. Mixtures that contain precursor chemicals identified in ECCN 1C350, in concentrations that are below the levels indicated in 1C350.b through .d, are controlled by ECCN 1C395 or 1C995 and are subject to the licensing requirements specified in those ECCNs.

b. A license is not required under this ECCN for a mixture, when the controlled chemical in the mixture is a normal ingredient in consumer goods packaged for retail sale for personal use. Such consumer goods are designated EAR99. However, a license may be required for reasons set forth elsewhere in the EAR.

Note to Mixtures: Calculation of concentrations of AG-controlled chemicals:

a. Exclusion. No chemical may be added to the mixture (solution) for the sole purpose of circumventing the Export Administration Regulations;

b. Percent Weight Calculation. When calculating the percentage, by weight, of ingredients in a chemical mixture, include all ingredients of the mixture, including those that act as solvents.

3. COMPOUNDS. Compounds created with any chemicals identified in this ECCN 1C350 may be shipped NLR (No License Required), without obtaining an End-Use Certificate, unless those compounds are also identified in this entry or require a license for reasons set forth elsewhere in the EAR.

4. TESTING KITS: Certain medical, analytical, diagnostic, and food testing kits containing small quantities of chemicals identified in this ECCN 1C350, are excluded from the scope of this ECCN and are controlled under ECCN 1C395 or 1C995. (Note that replacement reagents for such kits are controlled by this ECCN 1C350 if the reagents contain one or more of the precursor chemicals identified in 1C350 in concentrations equal to or greater than the control levels for mixtures indicated in 1C350.)

Technical Notes:

1. For purposes of this entry, a "mixture" is defined as a solid, liquid or gaseous product made up of two or more ingredients that do not react together under normal storage conditions.

2. The scope of this control applicable to Hydrogen Fluoride (see 1C350.d.14 in the List of Items Controlled) includes its liquid, gaseous, and aqueous phases, and hydrates.

3. Precursor chemicals in ECCN 1C350 are listed by name, Chemical Abstract Service (CAS) number and CWC Schedule (where applicable). Precursor chemicals of the same structural formula (e.g., hydrates, isotopically-labeled forms or all possible stereoisomers) are controlled by ECCN 1C350, regardless of name or CAS number. CAS numbers are shown to assist in identifying whether a particular precursor chemical or mixture is controlled under ECCN 1C350, irrespective of nomenclature. However, CAS numbers cannot be used as unique identifiers in all situations because some forms of the listed precursor chemical have different CAS numbers, and mixtures containing a precursor chemical listed in ECCN 1C350 may also have different CAS numbers.

List Based License Exceptions (See Part 740 for a description of all license exceptions)

LVS: N/A

GBS: N/A

List of Items Controlled

Related Controls: See USML Category XIV(c) for related chemicals "subject to the ITAR" (see 22 CFR parts 120 through 130).

Related Definitions: See § 770.2(k) of the EAR for synonyms for the chemicals listed in this entry.

Items:

a. [Reserved]

b. Australia Group-controlled precursor chemicals also identified as Schedule 2 chemicals under the CWC, as follows, and mixtures in which at least one of the following chemicals constitutes 30 percent or more of the weight of the mixture:

b.1. (C.A.S. #7784-34-1) Arsenic trichloride;

b.2. (C.A.S. #76-93-7) Benzilic acid;

b.3. (C.A.S. #78-38-6) Diethyl ethylphosphonate;

b.4. (C.A.S. #683-08-9) Diethyl methylphosphonate;

b.5. (C.A.S. #15715-41-0) Diethyl methylphosphonite;

b.6. (C.A.S. #2404-03-7) Diethyl-N,N-dimethylphosphoroamidate;

b.7. (C.A.S. #41480-75-5) N,N-Diisopropylaminoethanethiol hydrochloride;

b.8. (C.A.S. #5842-07-9) N,N-Diisopropyl-beta-aminoethane thiol;

b.9. (C.A.S. #96-80-0) N,N-Diisopropyl-beta-aminoethanol;

b.10. (C.A.S. #96-79-7), N,N-Diisopropyl-beta-aminoethyl chloride;

b.11. (C.A.S. #4261-68-1) N,N-Diisopropyl-beta-aminoethyl chloride hydrochloride;

b.12. (C.A.S. #6163-75-3) Dimethyl ethylphosphonate;

b.13. (C.A.S. #756-79-6) Dimethyl methylphosphonate;

b.14. (C.A.S. #677-43-0) N,N-dimethylamino-phosphoryl dichloride;

b.15. (C.A.S. #1498-40-4) Ethyl phosphonous dichloride [Ethyl phosphinyl dichloride];

b.16. (C.A.S. #430-78-4) Ethyl phosphonus difluoride [Ethyl phosphinyl difluoride];

b.17. (C.A.S. #1066-50-8) Ethyl phosphonyl dichloride;

b.18. (C.A.S. #993-13-5) Methylphosphonic acid;

b.19. (C.A.S. #676-98-2) Methylphosphonothioic dichloride.

b.20. (C.A.S. #464-07-3) Pinacolyl alcohol;

b.21. (C.A.S. #1619-34-7) 3-Quinuclidinol;

b.22. (C.A.S. #111-48-8) Thiodiglycol.

c. Australia Group-controlled precursor chemicals also identified as Schedule 3 chemicals under the CWC, as follows, and mixtures in which at least one of the following chemicals constitutes 30 percent or more of the weight of the mixture:

c.1. (C.A.S. #762-04-9) Diethyl phosphite;

c.2. (C.A.S. #868-85-9) Dimethyl phosphite (dimethyl hydrogen phosphite);

c.3. (C.A.S. #139-87-7) Ethyldiethanolamine;

c.4. (C.A.S. #10025-87-3) Phosphorus oxychloride;

c.5. (C.A.S. #10026-13-8) Phosphorus pentachloride;

c.6. (C.A.S. #7719-12-2) Phosphorus trichloride;

c.7. (C.A.S. #10545-99-0) Sulfur dichloride;

c.8. (C.A.S. #10025-67-9) Sulfur monochloride;

c.9. (C.A.S. #7719-09-7) Thionyl chloride;

c.10. (C.A.S. #102-71-6) Triethanolamine;

c.11. (C.A.S. #122-52-1) Triethyl phosphite;

c.12. (C.A.S. #121-45-9) Trimethyl phosphite.

d. Other Australia Group-controlled precursor chemicals not also identified as Schedule 1, 2, or 3 chemicals under the CWC, as follows, and mixtures in which at least one of the following chemicals constitutes 30 percent or more of the weight of the mixture:

d.1. (C.A.S. #1341-49-7) Ammonium hydrogen fluoride;

d.2. (C.A.S. #107-07-3) 2-Chloroethanol;

d.3. (C.A.S. #109-89-7) Diethylamine;

d.4. (C.A.S. #100-37-8) N,N-Diethylaminoethanol;

d.5. (C.A.S. #589-57-1) Diethyl chlorophosphite;

d.6. (C.A.S. #298-06-6) O,O-Diethyl phosphorodithioate;

d.7. (C.A.S. #2465-65-8) O,O-Diethyl phosphorothioate;

d.8. (C.A.S. #108-18-9) Di-isopropylamine;

d.9. (C.A.S. #124-40-3) Dimethylamine;

d.10. (C.A.S. #506-59-2) Dimethylamine hydrochloride;

d.11. (C.A.S. #762-77-6) Ethyl chlorofluorophosphate;

d.12. (C.A.S. #1498-51-7) Ethyl dichlorophosphate;

d.13. (C.A.S. #460-52-6) Ethyl difluorophosphate;

d.14. (C.A.S. #7664-39-3) Hydrogen fluoride;

d.15. (C.A.S. #3554-74-3) 3-Hydroxyl-1-methylpiperidine;

d.16. (C.A.S. #76-89-1) Methyl benzilate;

d.17. (C.A.S. #754-01-8) Methyl chlorofluorophosphate;

d.18. (C.A.S. #677-24-7) Methyl dichlorophosphate;

d.19. (C.A.S. #22382-13-4) Methyl difluorophosphate;

d.20. (C.A.S. #14277-06-6) N,N Diethylacetamidine;

d.21. (C.A.S. #53510-30-8) N,N-Diethylbutanamidine;

d.22. (C.A.S. #90324-67-7) N,N-Diethylformamidine;

d.23. (C.A.S. #1342789-47-2) N,N Diethylisobutanamidine;

d.24. (C.A.S. #84764-73-8) N,N-Diethylpropanamidine;

d.25. (C.A.S. #1315467-17-4) N,N-Diisopropylbutanamidine;

d.26. (C.A.S. #857522-08-8) N,N-Diisopropylformamidine;

d.27. (C.A.S. #2909-14-0) N,N-Dimethylacetamidine;

d.28. (C.A.S. #1340437-35-5) N,N-Dimethylbutanamidine;

d.29. (C.A.S. #44205-42-7) N,N-Dimethylformamidine;

d.30. (C.A.S. #321881-25-8) N,N-Dimethylisobutanamidine;

d.31. (C.A.S. #56776-14-8) N,N-Dimethylpropanamidine;

d.32. (C.A.S. #1339586-99-0) N,N-Dipropylacetamidine;

d.33. C.A.S. #1342422-35-8) N,N-Dipropylbutanamidine;

d.34. (C.A.S. #48044-20-8) N,N-Dipropylformamidine;

d.35. (C.A.S. #1342700-45-1) N,N-Dipropylisobutanamidine;

d.36. (C.A.S. #1341496-89-6) N,N-Dipropylpropanamidine;

d.37. (C.A.S. #1314-80-3) Phosphorus pentasulfide;

d.38. (C.A.S. #75-97-8) Pinacolone;

d.39. (C.A.S. #7789-29-9) Potassium bifluoride;

d.40. (C.A.S. #151-50-8) Potassium cyanide;

d.41. (C.A.S. #7789-23-3) Potassium fluoride;

d.42. (C.A.S. #3731-38-2) 3-Quinuclidone;

d.43. (C.A.S. #1333-83-1) Sodium bifluoride;

d.44. (C.A.S. #143-33-9) Sodium cyanide;

d.45. (C.A.S. #7681-49-4) Sodium fluoride;

d.46. (C.A.S. #16893-85-9) Sodium hexafluorosilicate;

d.47. (C.A.S. #1313-82-2) Sodium sulfide;

d.48. (C.A.S. #637-39-8) Triethanolamine hydrochloride;

d.49. (C.A.S. #116-17-6) Tri-isopropyl phosphite.

1C351 Human and animal pathogens and "toxins," as follows (see List of Items Controlled).

License Requirements

Reason for Control: CB, CW, AT

Control(s)	Country chart (See Supp. No. 1 to part 738)
CB applies to entire entry	CB Column 1

CW applies to 1C351.d.14 and .d.15 and a license is required for CW reasons for all destinations, including Canada, as follows: CW applies to 1C351.d.14 for ricin in the form of (1) Ricinus communis AgglutininII (RCA_{II}), also known as ricin D or Ricinus Communis LectinIII (RCL_{III}) and (2) Ricinus communis LectinIV (RCL_{IV}), also known as ricin E. CW applies to 1C351.d.15 for saxitoxin identified by C.A.S. #35523-89-8. See § 742.18 of the EAR for licensing information pertaining to chemicals subject to restriction pursuant to the Chemical Weapons Convention (CWC). The Commerce Country Chart is not designed to determine licensing requirements for items controlled for CW reasons.

Control(s)	Country chart (See Supp. No. 1 to part 738)
AT applies to entire entry	AT Column 1

LICENSE REQUIREMENT NOTES: *1. All vaccines and 'immunotoxins' are excluded from the scope of this entry. Certain medical products and diagnostic and food testing kits that contain biological toxins controlled under 1C351.d, with the exception of toxins controlled for CW reasons under 1C351.d.14 or .d.15, are excluded from the scope of this entry. Vaccines, 'immunotoxins,' certain medical products, and diagnostic and food testing kits excluded from the scope of this entry are controlled under ECCN 1C991.*

2. For the purposes of this entry, only saxitoxin is controlled under 1C351.d.15; other members of the paralytic shellfish poison family (e.g., neosaxitoxin) are designated EAR99.

3. Clostridium perfringens strains, other than the epsilon toxin-producing strains of

Clostridium perfringens described in 1C351.c.12, are excluded from the scope of this entry, since they may be used as positive control cultures for food testing and quality control.

4. Unless specified elsewhere in this ECCN 1C351 (e.g., in License Requirement Notes 1-3), this ECCN controls all biological agents and "toxins," regardless of quantity or attenuation, that are identified in the List of Items Controlled for this ECCN, including small quantities or attenuated strains of select biological agents or "toxins" that are excluded from the lists of select biological agents or "toxins" by the Animal and Plant Health Inspection Service (APHIS), U.S. Department of Agriculture (USDA), or the Centers for Disease Control and Prevention (CDC), U.S. Department of Health and Human Services (HHS), in accordance with their regulations in 9 CFR part 121 and 42 CFR part 73, respectively.

5. Biological agents and pathogens are controlled under this ECCN 1C351 when they are an isolated live culture of a pathogen agent, or a preparation of a toxin agent that has been isolated or extracted from any source or material, including living material that has been deliberately inoculated or contaminated with the agent. Isolated live cultures of a pathogen agent include live cultures in dormant form or in dried preparations, whether the agent is natural, enhanced or modified.

List Based License Exceptions (See Part 740 for a Description of All License Exceptions)

LVS: N/A

GBS: N/A

Special Conditions for STA

STA: (1) Paragraph (c)(1) of License Exception STA (§ 740.20(c)(1)) may be used for items in 1C351.d.1 through 1C351.d.13 and 1C351.d.16 through 1C351.d.21. See § 740.20(b)(2)(vi) for restrictions on the quantity of any one toxin that may be exported in a single shipment and the number of shipments that may be made to any one end user in a single calendar year. Also see the Automated Export System (AES) requirements in § 758.1(b)(4) of the EAR. (2) Paragraph (c)(2) of License Exception STA (§ 740.20(c)(2) of the EAR) may not be used for any items in 1C351.

List of Items Controlled

Related Controls: (1) Certain forms of ricin and saxitoxin in 1C351.d.14 and .d.15 are CWC Schedule 1 chemicals (see § 742.18 of the EAR). The U.S. Government must provide advance notification and annual reports to the OPCW of all exports of Schedule 1 chemicals. See § 745.1 of the EAR for notification procedures. See 22 CFR part 121, Category XIV and § 121.7 for CWC Schedule 1 chemicals that are "subject to the ITAR." (2) The Animal and Plant Health Inspection Service (APHIS), U.S. Department of Agriculture, and the Centers for Disease Control and Prevention (CDC), U.S. Department of Health and Human Services, maintain controls on the possession, use, and transfer within the United States of certain items controlled by this ECCN (for APHIS, see 7 CFR 331.3(b), 9 CFR 121.3(b), and 9 CFR 121.4(b); for CDC, see 42 CFR 73.3(b) and 42 CFR 73.4(b)). (3) See 22 CFR part 121, Category XIV(b), for modified biological agents and biologically derived substances that are "subject to the ITAR."

Related Definitions: For the purposes of this entry, 'immunotoxins' are monoclonal antibodies linked to a toxin with the intention of destroying a specific target cell while leaving adjacent cells intact.

Items:

a. Viruses identified on the Australia Group (AG) "List of Human and Animal Pathogens and Toxins for Export Control," as follows:

a.1. African horse sickness virus;

a.2. African swine fever virus;

a.3. Andes virus;

a.4. Avian influenza (AI) viruses identified as having high pathogenicity (HP), as follows:

a.4.a. AI viruses that have an intravenous pathogenicity index (IVPI) in 6-week-old chickens greater than 1.2; *or*

a.4.b. AI viruses that cause at least 75% mortality in 4- to 8-week-old chickens infected intravenously.

Note: *Avian influenza (AI) viruses of the H5 or H7 subtype that do not have either of the characteristics described in 1C351.a.4 (specifically, 1C351.a.4.a or .a.4.b) should be sequenced to determine whether multiple basic amino acids are present at the cleavage site of the haemagglutinin molecule (HA0). If the amino acid motif is similar to that observed for other HPAI isolates, then the isolate being tested should be considered as HPAI and the virus is controlled under 1C351.a.4.*

a.5. Bluetongue virus;

a.6. Chapare virus;

a.7. Chikungunya virus;

a.8. Choclo virus;

a.9. Classical swine fever virus (Hog cholera virus);

a.10. Crimean-Congo hemorrhagic fever virus;

a.11. Dobrava-Belgrade virus;

a.12. Eastern equine encephalitis virus;

a.13. Ebolavirus (includes all members of the Ebolavirus genus);

a.14. Foot-and-mouth disease virus;

a.15. Goatpox virus;

a.16. Guanarito virus;

a.17. Hantaan virus;

a.18. Hendra virus (Equine morbillivirus);

a.19. Japanese encephalitis virus;

a.20. Junin virus;

a.21. Kyasanur Forest disease virus;

a.22. Laguna Negra virus;

a.23. Lassa virus;

a.24. Louping ill virus;

a.25. Lujo virus;

a.26. Lumpy skin disease virus;

a.27. Lymphocytic choriomeningitis virus;

a.28. Machupo virus;

a.29. Marburgvirus (includes all members of the Marburgvirus genus);

a.30. Middle East respiratory syndrome-related coronavirus (MERS-related coronavirus);

a.31. Monkeypox virus;

a.32. Murray Valley encephalitis virus;

a.33. Newcastle disease virus;

a.34. Nipah virus;

a.35. Omsk hemorrhagic fever virus;

a.36. Oropouche virus;

a.37. Peste-des-petits ruminants virus;

a.38. Porcine Teschovirus;

a.39. Powassan virus;

a.40. Rabies virus and all other members of the Lyssavirus genus;

a.41. Reconstructed 1918 influenza virus;

Technical Note: *1C351.a.41 includes reconstructed replication competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments*.

a.42. Rift Valley fever virus;

a.43. Rinderpest virus;

a.44. Rocio virus;

a.45. Sabia virus;

a.46. Seoul virus;

a.47. Severe acute respiratory syndrome-related coronavirus (SARS-related coronavirus);

a.48. Sheeppox virus;

a.49. Sin Nombre virus;

a.50. St. Louis encephalitis virus;

a.51. Suid herpesvirus 1 (Pseudorabies virus; Aujeszky's disease);

a.52. Swine vesicular disease virus;

a.53. Tick-borne encephalitis virus (Far Eastern subtype, formerly known as Russian Spring-Summer encephalitis virus - see 1C351.b.3 for Siberian subtype);

a.54. Variola virus;

a.55. Venezuelan equine encephalitis virus;

a.56. Vesicular stomatitis virus;

a.57. Western equine encephalitis virus; *or*

a.58. Yellow fever virus.

b. Viruses identified on the APHIS/CDC "select agents" lists (see Related Controls paragraph #2 for this ECCN), but not identified on the Australia Group (AG) "List of Human and Animal Pathogens and Toxins for Export Control," as follows:

b.1. [Reserved];

b.2. [Reserved]; *or*

b.3. Tick-borne encephalitis virus (Siberian subtype, formerly West Siberian virus - see 1C351.a.53 for Far Eastern subtype).

c. Bacteria identified on the Australia Group (AG) "List of Human and Animal Pathogens and Toxins for Export Control," as follows:

c.1. Bacillus anthracis;

c.2. Brucella abortus;

c.3. Brucella melitensis;

c.4. Brucella suis;

c.5. Burkholderia mallei (Pseudomonas mallei);

c.6. Burkholderia pseudomallei (Pseudomonas pseudomallei);

c.7. Chlamydia psittaci (Chlamydophila psittaci);

c.8. Clostriduim argentinense (formerly known as Clostridium botulinum Type G), botulinum neurotoxin producing strains;

c.9. Clostridium baratii, botulinum neurotoxin producing strains;

c.10. Clostridium botulinum;

c.11. Clostridium butyricum, botulinum neurotoxin producing strains;

c.12. Clostridium perfringens, epsilon toxin producing types;

c.13. Coxiella burnetii;

c.14. Francisella tularensis;

c.15. Mycoplasma capricolum subspecies capripneumoniae (“strain F38”);

c.16. Mycoplasma mycoides subspecies mycoides SC (small colony) (a.k.a. contagious bovine pleuropneumonia);

c.17. Rickettsia prowazekii;

c.18. Salmonella enterica subspecies enterica serovar Typhi (Salmonella typhi);

c.19. Shiga toxin producing Escherichia coli (STEC) of serogroups O26, O45, O103, O104, O111, O121, O145, O157, and other shiga toxin producing serogroups;

Note: *Shiga toxin producing Escherichia coli (STEC) includes, inter alia, enterohaemorrhagic E. coli (EHEC), verotoxin producing E. coli (VTEC) or verocytotoxin producing E. coli (VTEC).*

c.20. Shigella dysenteriae;

c.21. Vibrio cholerae; *or*

c.22. Yersinia pestis.

d. "Toxins" identified on the Australia Group (AG) "List of Human and Animal Pathogens and Toxins for Export Control," as follows, or their subunits:

d.1. Abrin;

d.2. Aflatoxins;

d.3. Botulinum toxins;

d.4. Brevetoxins;

d.5. Clostridium perfringens alpha, beta 1, beta 2, epsilon and iota toxins;

d.6. Conotoxins;

d.7. Diacetoxyscirpenol;

d.8. Gonyautoxins;

d.9. HT-2 toxin;

d.10. Microcystins (Cyanginosins);

d.11. Modeccin;

d.12. Nodularins;

d.13. Palytoxin;

d.14. Ricin;

d.15. Saxitoxin;

d.16. Shiga toxins (shiga-like toxins, verotoxins, and verocytotoxins);

d.17. Staphylococcus aureus enterotoxins, hemolysin alpha toxin, and toxic shock syndrome toxin (formerly known as Staphylococcus enterotoxin F);

d.18. T-2 toxin;

d.19. Tetrodotoxin;

d.20. Viscumin (Viscum album lectin 1); *or*

d.21. Volkensin.

e. "Fungi", as follows:

e.1. Coccidioides immitis; *or*

e.2. Coccidioides posadasii.

* * * * *

1C353 Genetic elements and genetically modified organisms, as follows (see List of Items Controlled).

License Requirements

Reason for Control: CB, AT

Control(s)	Country Chart (See Supp. No. 1 to part 738)
CB applies to entire entry	CB Column 1
AT applies to entire entry	AT Column 1

License Requirements Notes:

1. Vaccines that contain genetic elements or genetically modified organisms identified in this ECCN are controlled by ECCN 1C991.

2. Unless specified elsewhere in this ECCN 1C353 (e.g., in License Requirement Note 1), this ECCN controls genetic elements or genetically modified organisms for all biological agents and "toxins," regardless of quantity or attenuation, that are identified in the List of Items Controlled for this ECCN, including genetic elements or genetically modified organisms for attenuated strains of select biological agents or "toxins" that are excluded from the lists of select biological agents or "toxins" by the Animal and Plant Health Inspection Service (APHIS), U.S. Department of Agriculture, or the Centers for Disease Control and Prevention (CDC), U.S. Department of Health and Human Services, in accordance with the APHIS regulations in 7 CFR part 331 and 9 CFR part 121 and the CDC regulations in 42 CFR part 73.

List Based License Exceptions (See Part 740 for a Description of All License Exceptions)

LVS: N/A

GBS: N/A

List of Items Controlled

Related Controls: (1) The Animal and Plant Health Inspection Service (APHIS), U.S. Department of Agriculture, and the Centers for Disease Control and Prevention (CDC), U.S. Department of Health and Human Services, maintain controls on the possession, use, and transfer within the United States of certain items controlled by this ECCN, including (but not limited to) certain genetic elements, recombinant nucleic acids, and recombinant organisms associated with the agents or toxins in ECCN 1C351 or 1C354 (for APHIS, see 7 CFR 331.3(c), 9 CFR 121.3(c), and 9 CFR 121.4(c); for CDC, see 42 CFR 73.3(c) and 42 CFR 73.4(c)). (2) See 22 CFR part 121, Category XIV(b), for modified biological agents and biologically derived substances that are subject to the export licensing jurisdiction of the U.S. Department of State, Directorate of Defense Trade Controls.

Related Definition: N/A

Items:

a. Any genetically modified organism that contains, or any genetic element that codes for, any of the following:

a.1. Any gene, genes, translated product or translated products specific to any virus controlled by 1C351.a or .b or 1C354.c;

a.2. Any gene or genes specific to any bacterium controlled by 1C351.c or 1C354.a, or any fungus controlled by 1C351.e or 1C354.b, and which;

a.2.a. In itself or through its transcribed or translated products represents a significant hazard to human, animal or plant health; *or*

a.2.b. Could endow or enhance pathogenicity; *or*

a.3. Any toxins, or their subunits, controlled by 1C351.d.

b. [Reserved].

Technical Notes:

1. Genetically modified organisms include organisms in which the nucleic acid sequences have been created or altered by deliberate molecular manipulation.

2. "Genetic elements" include, inter alia, chromosomes, genomes, plasmids, transposons, vectors, and inactivated organisms containing recoverable nucleic acid fragments, whether genetically modified or unmodified, or chemically synthesized in whole or in part. For the purposes of this ECCN 1C353, nucleic acids from an inactivated organism, virus, or sample are considered to be 'recoverable' if the inactivation and preparation of the material is intended or known to facilitate isolation, purification, amplification, detection, or identification of nucleic acids.

3. This ECCN does not control nucleic acid sequences of shiga toxin producing Escherichia coli of serogroups O26, O45, O103, O104, O111, O121, O145, O157, and other shiga toxin producing serogroups, other than those genetic elements coding for shiga toxin, or for its subunits.

4. 'Endow or enhance pathogenicity' is defined as when the insertion or integration of the nucleic acid sequence or sequences is/are likely to enable or increase a recipient organism's ability to be used to deliberately cause disease or death. This might include alterations to, *inter alia*: virulence, transmissibility, stability, route of infection, host range, reproducibility, ability to evade or suppress host immunity, resistance to medical countermeasures, or detectability.

1C354 Plant pathogens, as follows (see List of Items Controlled).

License Requirements

Reason for Control: CB, AT

Control(s)	Country Chart (See Supp. No. 1 to part 738)
CB applies to entire entry	CB Column 1
AT applies to entire entry	AT Column 1

***License Requirements Notes*:**

1. All vaccines are excluded from the scope of this ECCN. See ECCN 1C991 for vaccines.

2. Unless specified elsewhere in this ECCN 1C354 (e.g., in License Requirement Note 1), this ECCN controls all biological agents, regardless of quantity or attenuation, that are identified in the List of Items Controlled for this ECCN, including small quantities or attenuated strains of select biological agents that are excluded from the list of PPQ select agents and "toxins" by the Animal and Plant Health Inspection Service (APHIS), U.S. Department of Agriculture, in accordance with their regulations in 7 CFR part 331.

List Based License Exceptions (See Part 740 for a description of all license exceptions)

LVS: N/A

GBS: N/A

List of Items Controlled

Related Controls: (1) The Animal and Plant Health Inspection Service (APHIS), U.S. Department of Agriculture, maintains controls on the possession, use, and transfer within the United States of certain items controlled by this ECCN (see 7 CFR 331.3(c), 9 CFR 121.3(c), and 9 CFR 121.4(c)). (2) See 22 CFR part 121, Category XIV(b), for modified biological agents and biologically derived substances that are subject to the export licensing jurisdiction of the U.S. Department of State, Directorate of Defense Trade Controls.

Related Definitions: N/A

Items:

a. Bacteria, as follows:

a.1. *Xanthomonas albilineans*;

a.2. *Xanthomonas citri pv. citri (Xanthomonas axonopodis* pv. *citri, Xanthomonas campestris* pv. *citri)*;

a.3. *Xanthomonas oryzae* [this species of proteobacteria is identified on the APHIS "select agents" list (see Related Controls paragraph for this ECCN), but only the pathovar *Xanthomonas oryzae* pv. *oryzae* (syn. *Pseudomonas campestris* pv. *oryzae*) is identified on the Australia Group (AG) "List of Plant Pathogens for Export Control"];

a.4. *Clavibacter michiganensis* subsp. *sepedonicus* (*Clavibacter sepedonicus*, *Clavibacter michiganense* subsp. *sepedonicus*, *Corynebacterium michiganensis* subsp. *sepedonicum*, *Corynebacterium sepedonicum*);

a.5. *Ralstonia solanacearum*, race 3, biovar 2;

a.6. *Raythayibactor toxicus* [this bacterium is identified on the APHIS "select agents" list (see the Related Controls paragraph for this ECCN), but is not identified on the Australia Group (AG) "List of Plant Pathogens for Export Control"].

b. Fungi, as follows:

b.1. *Bipolaris oryzae* (*Cochliobolus miyabeanus*, *Helminthosporium oryzae*);

b.2. *Colletotrichum kahawae* (*Colletotrichum coffeanum* var. *virulans*);

b.3. *Pseudocercospora ulei* (*Microcyclus ulei, Dothidella ulei*);

b.4. *Puccinnia graminis* ssp. *graminis* var. *graminis/Puccinia graminis* ssp. *graminis* var. *stakmanii* (*Puccinia graminis* [syn. *Puccinia graminis* f. sp. *tritici*]);

b.5. *Puccinia striiformis* (syn. *Puccinia glumarum*);

b.6. *Magnaporthe oryzae* (Pyricularia oryzae);

b.7. *Peronosclerospora philippinensis* (*Peronosclerospora sacchari*);

b.8. *Sclerophthora rayssiae* var. *zeae*;

b.9. *Synchytrium endobioticum*;

b.10. *Tilletia indica*;

b.11. *Thecaphora solani*;

b.12. *Phoma glycinicola* (formerly *Pyrenochaeta glycines*) [this fungus is identified on the APHIS "select agents" list (see the Related Controls paragraph for this ECCN), but is not identified on the Australia Group (AG) "List of Plant Pathogens for Export Control"].

c. Viruses, as follows:

c.1. Andean potato latent virus (Potato Andean latent tymovirus);

c.2. Potato spindle tuber viroid.

* * * * *

1C991 Vaccines, immunotoxins, medical products, diagnostic and food testing kits, as follows (see List of Items Controlled).

License Requirements

Reason for Control: CB, AT

Control(s)	Country Chart (See Supp. No. 1 to part 738)
CB applies to 1C991.c	CB Column 3
AT applies to entire entry	AT Column 1

List Based License Exceptions (See Part 740 for a Description of All License Exceptions)

LVS: N/A

GBS: N/A

List of Items Controlled

Related Controls: (1) Medical products containing ricin or saxitoxin, as follows, are controlled for CW reasons under ECCN 1C351:

(a) Ricinus communis AgglutininII (RCA_{II}), also known as ricin D, or Ricinus Communis LectinIII (RCL_{III});

(b) Ricinus communis LectinIV (RCL_{IV}), also known as ricin E; *or*

(c) Saxitoxin identified by C.A.S. #35523-89-8.

(2) The export of a "medical product" that is an "Investigational New Drug" (IND), as defined in 21 CFR 312.3, is subject to certain U.S. Food and Drug Administration (FDA) requirements that are independent of the export requirements specified in this ECCN or elsewhere in the EAR. These FDA requirements are described in 21 CFR 312.110 and must be satisfied in addition to any requirements specified in the EAR.

(3) Also see 21 CFR 314.410 for FDA requirements concerning exports of new drugs and new drug substances.

Related Definitions: For the purpose of this entry, 'immunotoxins' are monoclonal antibodies linked to a toxin with the intention of destroying a specific target cell while leaving adjacent cells intact. For the purpose of this entry, 'medical products' are: (1) Pharmaceutical formulations designed for testing and human (or veterinary) administration in the treatment of

medical conditions; (2) prepackaged for distribution as clinical or medical products; and (3) approved by the U.S. Food and Drug Administration either to be marketed as clinical or medical products or for use as an "Investigational New Drug" (IND) (see 21 CFR part 312). For the purpose of this entry, 'diagnostic and food testing kits' are specifically developed, packaged and marketed for diagnostic or public health purposes. Biological toxins in any other configuration, including bulk shipments, or for any other end-uses are controlled by ECCN 1C351. For the purpose of this entry, 'vaccine' is defined as a medicinal (or veterinary) product in a pharmaceutical formulation, approved by the U.S. Food and Drug Administration or the U.S. Department of Agriculture to be marketed as a medical (or veterinary) product or for use in clinical trials, that is intended to stimulate a protective immunological response in humans or animals in order to prevent disease in those to whom or to which it is administered.

Items:

Technical Note: *For purposes of the controls described in this ECCN, 'toxins' refers to those toxins, or their subunits, controlled under ECCN 1C351.d.*

a. Vaccines containing, or designed for use against, items controlled by ECCN 1C351, 1C353 or 1C354.

b. Immunotoxins containing toxins controlled by 1C351.d;

c. Medical products that contain any of the following:

c.1. Toxins controlled by ECCN 1C351.d (except for botulinum toxins controlled by ECCN 1C351.d.3, conotoxins controlled by ECCN 1C351.d.6, or items controlled for CW reasons under

ECCN 1C351.d.14 or .d.15); *or*

c.2. Genetically modified organisms or genetic elements controlled by ECCN 1C353.a.3 (except for those that contain, or code for, botulinum toxins controlled by ECCN 1C351.d.3 or conotoxins controlled by ECCN 1C351.d.6);

d. Medical products not controlled by 1C991.c that contain any of the following:

d.1. Botulinum toxins controlled by ECCN 1C351.d.3;

d.2. Conotoxins controlled by ECCN 1C351.d.6; *or*

d.3. Genetically modified organisms or genetic elements controlled by ECCN 1C353.a.3 that contain, or code for, botulinum toxins controlled by ECCN 1C351.d.3 or conotoxins controlled by ECCN 1C351.d.6;

e. Diagnostic and food testing kits containing toxins controlled by ECCN 1C351.d (except for items controlled for CW reasons under ECCN 1C351.d.14 or .d.15).

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2B352 Equipment Capable of Use in Handling Biological Materials, as Follows (See List of Items Controlled).

License Requirements

Reason for Control: CB, AT

Control(s)	Country chart (See Supp. No. 1 to part 738)
CB applies to entire entry	CB Column 2
AT applies to entire entry	AT Column 1

List Based License Exceptions (See Part 740 for a Description of All License Exceptions)

LVS: N/A

GBS: N/A

List of Items Controlled

Related Controls: See ECCNs 1A004 and 1A995 for protective equipment that is not covered by this entry. Also see ECCN 9A120 for controls on certain "UAV" systems designed or modified to dispense an aerosol and capable of carrying elements of a payload in the form of a particulate or liquid, other than fuel "parts" or "components" of such vehicles, of a volume greater than 20 liters.

Related Definitions: (1) "Lighter than air vehicles" - balloons and airships that rely on hot air or on lighter-than-air gases, such as helium or hydrogen, for their lift. (2) "UAVs" - Unmanned Aerial Vehicles. (3) "VMD" - Volume Median Diameter.

Items:

a. Containment facilities and related equipment, as follows:

a.1. Complete containment facilities at P3 or P4 containment level.

Technical Note to 2B352.a.1: *P3 or P4 (BL3, BL4, L3, L4) containment levels are as specified in the WHO Laboratory Biosafety Manual (3rd edition, Geneva, 2004).*

a.2. Equipment designed for fixed installation in containment facilities specified in paragraph a.1 of this ECCN, as follows:

a.2.a. Double-door pass-through decontamination autoclaves;

a.2.b. Breathing air suit decontamination showers;

a.2.c. Mechanical-seal or inflatable-seal walkthrough doors.

b. Fermenters and components as follows:

b.1. Fermenters capable of cultivation of micro-organisms or of live cells for the production of viruses or toxins, without the propagation of aerosols, having a total internal volume of 20 liters or greater.

b.2. Components designed for such fermenters, as follows:

b.2.a. Cultivation chambers designed to be sterilized or disinfected in situ;

b.2.b. Cultivation chamber holding devices; *or*

b.2.c. Process control units capable of simultaneously monitoring and controlling two or more fermentation system parameters (*e.g.,* temperature, pH, nutrients, agitation, dissolved oxygen, air flow, foam control).

Technical Notes to 2B352.b:

1. Fermenters include bioreactors (including single-use (disposable) bioreactors), chemostats and continuous-flow systems.

2. Cultivation chamber holding devices controlled by 2B352.b.2.b include single-use cultivation chambers with rigid walls.

c. Centrifugal separators capable of the continuous separation of pathogenic microorganisms, without the propagation of aerosols, and having all of the following characteristics:

c.1. One or more sealing joints within the steam containment area;

c.2. A flow rate greater than 100 liters per hour;

c.3. "Parts" or "components" of polished stainless steel or titanium; *and*

c.4. Capable of in-situ steam sterilization in a closed state.

Technical Note to 2B352.c: *Centrifugal separators include decanters.*

d. Cross (tangential) flow filtration equipment and "accessories", as follows:

d.1. Cross (tangential) flow filtration equipment capable of separation of microorganisms, viruses, toxins or cell cultures having all of the following characteristics:

d.1.a. A total filtration area equal to or greater than 1 square meter (1 m^2); *and*

d.1.b. Having any of the following characteristics:

d.1.b.1. Capable of being sterilized or disinfected in-situ; *or*

d.1.b.2. Using disposable or single-use filtration "parts" or "components".

N.B.: *2B352.d.1 does not control reverse osmosis and hemodialysis equipment, as specified by the manufacturer.*

d.2. Cross (tangential) flow filtration "parts" or "components" (e.g., modules, elements,

cassettes, cartridges, units or plates) with filtration area equal to or greater than 0.2 square meters (0.2 m^2) for each "part" or "component" and designed for use in cross (tangential) flow filtration equipment controlled by 2B352.d.1.

Technical Note: In this ECCN, "sterilized" denotes the elimination of all viable microbes from the equipment through the use of either physical (e.g., steam) or chemical agents. "Disinfected" denotes a process to reduce the number of microorganisms, but not usually of bacterial spores, through the use of chemical agents, without necessarily killing or removing all organisms.

e. Steam, gas or vapor sterilizable freeze-drying equipment with a condenser capacity of 10 kg of ice or greater in 24 hours (10 liters of water or greater in 24 hours) and less than 1000 kg of ice in 24 hours (less than 1,000 liters of water in 24 hours).

f. Spray-drying equipment capable of drying toxins or pathogenic microorganisms having all of the following characteristics:

f.1. A water evaporation capacity of ≥0.4 kg/h and ≤400 kg/h;

f.2. The ability to generate a typical mean product particle size of ≤10 micrometers with existing fittings or by minimal modification of the spray-dryer with atomization nozzles enabling generation of the required particle size; *and*

f.3. Capable of being sterilized or disinfected in situ.

g. Protective and containment equipment, as follows:

g.1. Protective full or half suits, or hoods dependent upon a tethered external air supply and operating under positive pressure.

Technical Note to 2B352.g.1: 2B352.g.1 does not control suits designed to be worn with self-contained breathing apparatus.

g.2. Biocontainment chambers, isolators, or biological safety cabinets having all of the following characteristics, for normal operation:

g.2.a. Fully enclosed workspace where the operator is separated from the work by a physical barrier;

g.2.b. Able to operate at negative pressure;

g.2.c. Means to safely manipulate items in the workspace; *and*

g.2.d. Supply and exhaust air to and from the workspace is high-efficiency particulate air (HEPA) filtered.

Note 1 to 2B352.g.2: 2B352.g.2 controls class III biosafety cabinets, as specified in the WHO Laboratory Biosafety Manual (3rd edition, Geneva, 2004) or constructed in accordance with national standards, regulations or guidance.

Note 2 to 2B352.g.2: 2B352.g.2 controls any isolator having all of the characteristics described in 2B352.g.2.a through g.2.d, regardless of its intended use and its designation, except for medical isolators "specially designed" for barrier nursing or transportation of infected patients.

h. Aerosol inhalation equipment designed for aerosol challenge testing with microorganisms, viruses or toxins, as follows:

h.1. Whole-body exposure chambers having a capacity of 1 cubic meter or greater;

h.2. Nose-only exposure apparatus utilizing directed aerosol flow and having a capacity

for the exposure of 12 or more rodents, or two or more animals other than rodents, and closed animal restraint tubes designed for use with such apparatus.

i. Spraying or fogging systems and "parts" and "components" therefor, as follows:

i.1. Complete spraying or fogging systems, "specially designed" or modified for fitting to aircraft, "lighter than air vehicles," or "UAVs," capable of delivering, from a liquid suspension, an initial droplet "VMD" of less than 50 microns at a flow rate of greater than 2 liters per minute;

i.2. Spray booms or arrays of aerosol generating units, "specially designed" or modified for fitting to aircraft, "lighter than air vehicles," or "UAVs," capable of delivering, from a liquid suspension, an initial droplet "VMD" of less than 50 microns at a flow rate of greater than 2 liters per minute;

i.3. Aerosol generating units "specially designed" for fitting to the systems as specified in paragraphs i.1 and i.2 of this ECCN.

Technical Notes to 2B352.i:

1. Aerosol generating units are devices "specially designed" or modified for fitting to aircraft and include nozzles, rotary drum atomizers and similar devices.

2. This ECCN does not control spraying or fogging systems, "parts" and "components," as specified in 2B352.i, that are demonstrated not to be capable of delivering biological agents in the form of infectious aerosols.

3. Droplet size for spray equipment or nozzles "specially designed" for use on aircraft or "UAVs" should be measured using either of the following methods (pending the adoption of internationally accepted standards):

a. Doppler laser method,

b. Forward laser diffraction method.

j. Nucleic acid assemblers and synthesizers that are both:

j.1 Partly or entirely automated; *and*

j.2. Designed to generate continuous nucleic acids greater than 1.5 kilobases in length with error rates less than 5% in a single run.

* * * * *

Thea D. Rozman Kendler

Assistant Secretary
for Export Administration

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